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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,632	BAROLI ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,12,21,22,25-33,39,48,49,52-62,73,74 and 77-81* is/are pending in the application.

4a) Of the above claim(s) *60-62,73,74 and 77-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,12,21,22,25-33,39,48,49 and 52-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 10/10/07 to claims 1, 3, 21, 22, 25-29, 32, 48, 49, 52-56, 60, 73, 74, and 77-81 have been entered. Claims 2, 4, 5, 7-11, 13-20, 23, 24, 34-38, 40-47, 50, 51, 63-72, 75, and 76 have been cancelled. No claims have been added. Claims 1, 3, 6, 12, 21, 22, 25-33, 39, 48, 49, 52-62, 73, 74, and 77-81 remain pending in the current application, of which claims 1, 3, 6, 12, 21, 22, 25-33, 39, 48, 49, and 52-59 ONLY are being considered on their merits. Claims 60-62, 73, 74, and 77-81 remain withdrawn from consideration at this time. Prior art references not included with this Office action can be found in a prior action.

Election/Restrictions

Applicant's election with traverse of the species "tissue engineering," "gelatin," "protein," "sugar," "polyethylene glycol," "cross-linked synthetic polymer," "granulation," "visible radiation," and "dissolution-controlled systems" in the reply filed on 4/23/07 is still in effect over the claims.

Applicant disputes the status of claims 60-62, 73, 74, and 77-81. These claims are indeed withdrawn because they are drawn to nonelected species (j) "drug," which applicant had the opportunity to elect in response to the 1/10/07 restriction requirement. Instead, applicant elected species (k), "protein." Now-canceled claim 10 was drawn to an embodiment of claim 1 wherein the bioactive species is a drug; claim 60 is identical in scope to now-canceled claim 10. Furthermore, at the bottom of page 3 of the Office action mailed 7/10/07, the examiner explained her reasoning for withdrawing claim 60

and its dependents; claims 60-62, 73, 74, and 77-81 are not included in the list of claims being considered on their merits as set forth at the top of page 4 of said Office action; and claims 60-62, 73, 74, and 77-81 are included in the list of withdrawn claims in the PTOL-326 accompanying said Office action. Claims 60-62, 73, 74, and 77-81, like claim 10, were withdrawn by the examiner and should be provided with appropriate status identifiers in future replies. Failure to designate these claims as withdrawn claims will constitute a noncompliant reply.

Claims 1, 3, 6, 12, 21, 22, 25-33, 39, 48, 49, and 52-59 are currently under examination on their merits, to the extent they read on the elected species where applicable.

Drawings

The drawings were received on 10/10/07. These drawings are acceptable.

Specification

The objections to the specification are withdrawn in light of the amendments to the specification and the submission of a new abstract.

Claim Objections

The objection to the claims is withdrawn in light of the corrections to claims 25, 26, 52, and 53. The examiner thanks applicant for providing double-spaced claims.

Claim Rejections - 35 USC § 112

Any rejections of record under 35 U.S.C. § 112, second paragraph, not specifically addressed below are withdrawn in light of the claim amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 6, 12, 21, 22, 25-33, 39, 48, 49, and 52-59 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 may be interpreted as being drawn to a product comprising three components ("monomers", "bioactive molecules", and "insoluble material"), but it also includes a limitation regarding the properties of the composition "upon polymerization" and one regarding the action of the insoluble material "during the polymerization process." It is not clear whether the claim means to describe the composition prior to polymerization or after polymerization or both. Even after the claim amendments, it is not clear whether applicant means to claim a solid composition comprising monomers, bioactive molecules, and insoluble material or a gel composition comprising polymerized monomers. The dependent claims further confuse the issue, since some appear to limit the solid composition comprising monomers (claims 30 and 31), some limit the gel composition comprising polymers (claims 25 and 26), and some limit the intermediate product during the polymerization process (claims 21, 22, 27-31). Claim 31 requires that the composition comprise "visible radiation," implying that an apparatus of some sort is being claimed, since light cannot be "comprised" by any composition. Clarification is required. The claim should be amended such that the composition being claimed is particularly pointed out.

In addition, the amendment to claim 1 introduces method steps ("is administered"), which leads to further confusion as to the scope of the claim. The claim

should be amended such that it does not recite both a product and a method, as it currently does. Clarification is required.

Because claims 3, 6, 12, 21, 22, and 25-31 depend from indefinite claim 1 and do not clarify this point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Applicant's arguments regarding the rejections of record have been considered, but none of them appears to address the particular point of confusion discussed above.

Claim 3 appears to recite both a product and a method of using a product, which is improper. A single claim that claims both a product or apparatus and the method steps of using said product or apparatus is indefinite under 35 U.S.C. § 112, second paragraph. See *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), and M.P.E.P. § 2173.05(p). Clarification is required. If claim 3 is intended to require that the composition of claim 1 be suitable for tissue engineering, it should be amended to read so and should indicate which properties render the composition so suitable and are not inherently present in claim 1.

Claim 3 recites the limitation "the subject's tissue" at line 2, which lacks antecedent basis in claim 1. Claim 1 does not recite a subject. Clarification is required.

It is not clear how the composition of claim 1 could be used to replace, repair, or restructure tissue. Clarification is required.

The nature of the "protection" afforded by the binder in claim 21 is not clear. Clarification is required.

The nature of the "protection" afforded by the granulated particles in claim 29 is not clear. Furthermore, it is not clear whether claim 29 further describes the physical form of the insoluble material or whether claim 29 requires that the insoluble material further comprise some additional granulated particles. Clarification is required.

Claim 32 may be interpreted as being drawn to a product comprising three components ("monomers", "bioactive molecules", and "insoluble material"), but it also includes a limitation regarding the properties of the composition "upon polymerization" and one regarding the action of the insoluble material "during the polymerization process." It is not clear whether the claim means to describe the composition prior to polymerization or after polymerization or both. Even after the claim amendments, it is not clear whether applicant means to claim a solid composition comprising monomers, bioactive molecules, and insoluble material or a gel composition comprising polymerized monomers. The dependent claims further confuse the issue, since some appear to limit the solid composition comprising monomers (claims 58 and 59), some limit the gel composition comprising polymers (claims 52 and 53), and some limit the intermediate product during the polymerization process (claims 48, 49, and 54-59). Claim 59 requires that the composition comprise "visible radiation," implying that an apparatus of some sort is being claimed, since light cannot be "comprised" by any composition. Clarification is required. The claim should be amended such that the composition being claimed is particularly pointed out.

In addition, the amendment to claim 32 introduces method steps ("is administered"), which leads to further confusion as to the scope of the claim. The claim

should be amended such that it does not recite both a product and a method, as it currently does. Clarification is required.

Finally, claim 32 has been amended such that it is identical to claim 1, except that it contains "monomers," "a drug-loaded delivery system comprising bioactive molecules," and "insoluble material." It is not clear how the "drug-loaded delivery system comprising bioactive molecules" of claim 32 is different from the "bioactive molecules" of claim 1. It is not clear, for example, whether the "drug-loaded delivery system" comprises additional components, or whether it necessarily has a different physical form. Clarification is required.

Because claims 33, 39, 48, 49, and 52-59 depend from indefinite claim 32 and do not clarify this point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

The nature of the "protection" afforded by the binder in claim 48 is not clear. Clarification is required.

The nature of the "protection" afforded by the granulated particles in claim 29 is not clear. Furthermore, it is not clear whether claim 29 further describes the physical form of the insoluble material or whether claim 29 requires that the insoluble material further comprise some additional granulated particles. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 6, 12, 21, 22, 25-33, 39, 48, 49, and 52-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (2003, U.S. Patent Application Publication 2003/0236573; reference A). It is noted that the claims are so indefinite (see above) that they nearly preclude a meaningful art search. However, in the interest of compact prosecution, the examiner has interpreted the claims for art rejections as being drawn to a solid composition only, i.e. a composition that has not been implanted into an organism, and not to any method or apparatus. For the purpose of this rejection only, the claims are interpreted as being drawn to a composition comprising photopolymerizable monomers, bioactive molecules, and a material insoluble by the monomers. In some dependent claims, the bioactive molecule is a protein and the insoluble material is gelatin. In some dependent claims, In some dependent claims, the composition further comprises a binder (e.g., a sugar), a plasticizer (e.g., polyethylene glycol), a disaggregant (e.g., a cross-linked synthetic polymer), granulated particles, or a photopolymerization means (e.g., visible radiation).

Evans teaches a flowable implant for treating tissue defects (paragraphs 139 and 140, e.g.). The composition of Evans may include a growth factor (i.e., a bioactive

protein), gelatin (which is both an insoluble material and a bioactive protein), and a photopolymerizable monomer (e.g., FOCALSEAL) (see paragraph 139). Evans contemplates an embodiment in which the implant treats a tissue defect only at body temperature (paragraphs 127 and 139). The composition of Evans may further include polyethylene glycol as a filler (Table 4 at paragraph 7) and may include plasticizers other than polyethylene glycol, many of which are also cross-linked synthetic polymers (Table 5 at paragraph 108). The composition of Evans may comprise sugars (paragraph 171). The composition of Evans may include nanoparticles (i.e., granules) of any of numerous components (Table 5 at paragraph 109). The composition of Evans inherently comprises light, i.e. the light in the laboratory in which it is prepared.

The limitations "wherein the binder binds the insoluble material to protect the bioactive molecules" (claims 21 and 48), "wherein the plasticizer increases the flexibility of the cross-linked structure" (claims 25 and 52), and "wherein the disaggregant aids with the solid-gel transition" (claims 27 and 54) all recite inherent properties of these components. A plasticizer, by definition, increases the flexibility of compositions. These limitations do not describe these components in structural terms. The limitations "wherein the insoluble material protects the bioactive molecules" (claims 1 and 32) and "wherein the granules protect the bioactive molecules" (claims 29 and 56) do not particularly point out the nature of the protection; a composition comprising an insoluble material and bioactive molecules necessarily "protects" at least some of the bioactive molecules, since at least some of them are mixed with the insoluble material and

"protected" from the air, as opposed to a composition consisting of bioactive molecules only.

A person of ordinary skill in the art would have had a reasonable expectation of success in making a composition comprising a bioactive protein, a photopolymerizable monomer, a insoluble material insoluble in the monomers, a binder such as a sugar, a plasticizer such as polyethylene glycol, any of numerous cross-linked synthetic polymers, granules of any of numerous components, and a photopolymerization means such as the light in the laboratory because Evans teaches that all of these components may be included in a flowable implant that may be administered into a patient's body to treat a tissue defect. The selection of the components and the amounts thereof would have constituted routine optimization on the part of the person of ordinary skill in the art, said artisan recognizing that Evans teaches that the composition may be modified to be compatible with the defective tissue being treated and to mimic said tissue's properties (paragraph 110, e.g.). The disclosure of Evans is broad and inclusive; Evans contemplates optimization of the components to be included and the conditions to be treated (paragraph 113, e.g.). A holding of obviousness over the cited claims is therefore clearly required. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's remarks regarding the withdrawn art rejection of record have been considered to the extent they read on this new ground of rejection. Applicant alleges

generally that the cited prior art does not teach the composition of claim 1 (Reply, page 18, paragraphs 1 and 3). These arguments have been fully considered, but they are not persuasive.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The arguments set forth by applicant do not set forth, e.g. by column and line number or paragraph number, the specific differences between the cited prior art and the claims. The reply to this Office action should include arguments citing specific ways in which the Evans reference does not teach the claimed composition. Applicant is urged in the strongest possible terms to claim the components of the claimed composition in structural, not functional, terms and to clearly set forth the physical configuration of the composition in the claims. A general statement that Evans does not teach or suggest the invention is insufficient. In the arguments of record, applicant points out what is taught by the prior art but fails to correlate these teachings with specific differences in the claimed composition. Such arguments would be useful in assisting the examiner in identifying the nature of the invention and identifying allowable subject matter if such exists in the application, since the instant claims are extremely broad and indefinite and do not permit substantive examination.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart
Examiner/Partial Signatory Authority
Temporary Full Signatory Authority (as of 12/9/07)